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**REMARKS**

Claims 45 and 46 have been cancelled. Claims 1-44, and 47-49 are now pending in the application. Claims 1, 3, 4, 5, 6, 8, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 30, 31, 32, 33, 35, 36, 37, 40, 41, 42, 43, 47, 48, and 49 have been amended. No new matter has been added by amendment. Reexamination and reconsideration of the claims as amended are respectfully requested.

**CLAIM OBJECTIONS**

1) Examiner objects to claims 8 and 27 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative. Claims 8 and 27 have been amended and no longer refer to two claims. The amendments place claims 8 and 27 in proper form.

**REJECTIONS - DOUBLE PATENTING**

2) Examiner rejects claims 1-49 under the "doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,118,056 ('056)." Applicants traverse the rejection. Examiner states, "Although the conflicting claims are not identical, they are not patentably distinct from each other because they both appear to be drawn to the same maize seeds, plants, plant parts and methods. The instantly claimed plants and the patented plants have different designations. The designation 'PH6ME' of the instantly claimed cultivar is arbitrarily assigned, and does not provide any patentable distinction from the cultivar claimed in '056, PH1EM. Any differences between PH6ME and PH1EM are due to minor morphological variations that do not confer patentable distinction." Applicants point out that the designation "PH6ME" of the instantly claimed cultivar is not arbitrarily assigned. PH6ME seed has been deposited with the ATCC and the specification and the appropriate claims have been amended to include the ATCC deposit number. Applicants also point out that the differences between PH6ME and PH1EM are not "minor morphological variations. On page 17, lines 4-5, of the specification it states that PH6ME is best suited to be used as a male for producing hybrids. In column 10, lines 51-53 of the '056 patent it states that PH1EM is best suited to be used as a female for producing hybrids. Other differences are taken from Table 1 of the specification, pages 18-20, and Table 1 of the '056 patent, columns 11-15 and are listed in the following table.

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PH6ME		PH1EM
Silk color is pink		Silk color is light green
Anther color is yellow		Anther color is red
Glume color is pink		Glume color is light green
Tassel length is 50 cm long		Tassel length is 62 cm long
7 = Fusarium ear and kernel rot resistance score		5 = Fusarium ear and kernel rot resistance score
6 = 1 <sup>st</sup> generation European Corn Borer feeding score		3 = 1 <sup>st</sup> generation European Corn Borer feeding score

The examples and the list are not exhaustive but they give ample evidence that the inventions are not the same. Nor are they minor variations of each other.

Examiner goes on to state that, "The instantly claimed plants that are derived from crosses and breeding programs involving PH6ME or plants having the same morphological and physiological characteristics of PH6ME, and plants produced by genetic transformation of PH6ME, are not patentably distinct from the patented plants that are derived from crosses and breeding programs involving PH1EM or plants having the same morphological and physiological characteristics of PH1EM, and plants produced by genetic transformation of PH1EM." Applicants respectfully disagree with the Examiner. Applicants submit that PH6ME is clearly differentiated from PH1EM. One would not be able to obtain PH6ME through modification of the maize inbred taught in patent '056 because PH6ME comprises a unique and nonobvious combination of previously unknown and nonobvious genetics. Further, plants derived from PH6ME are also clearly differentiated. The corn genome contains enormous complexity, and it is not possible that the claimed plants derived from PH6ME could have been produced without the use of PH6ME. In particular, PH1EM could not be substituted as the starting material to produce the claimed plants derived from PH6ME. For example, a plant that is one cross away from PH6ME would retain, on average, 50% of its genetic contribution from PH6ME. These genetics would comprise linkage groups and polymorphisms unique to PH6ME, as it would be impossible to completely remove the contribution of PH6ME to its progeny within one breeding cycle.

Examiner goes on to state that, "The instantly claimed methods are also not patentably distinct from the patented methods, as the plants used in the methods are not patentably distinct, and involve the same steps." Applicants point out that the use of the unique invention PH6ME in the breeding process is, in itself, an improvement of the breeding process. The Applicants have assembled a unique combination of genetics in PH6ME that benefits those using PH6ME as starting material in a breeding program.

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Examiner goes on to state that, "The claims of '056 include a method of producing a maize plant comprising crossing a maize plant, having all the morphological and physiological characteristics of PH1EM wherein the plant has been transformed with a transgene, with a non-transformed plant of line PH1EM. Note that plants produced by crossing a transformed PH1EM plant with a non-transformed PH1EM plant are PH1EM plants with a single gene conversion. ... A patent issuing from the instant application would then effectively extend the term of the claims of '056." Applicants point out that PH6ME and PH1EM are not the same invention nor is PH6ME a minor derivation of PH1EM. Applicants further point out that PH6ME is not a PH1EM plant comprising a single gene conversion. Please see evidence of such, stated above.

In light of the above, Applicants respectfully request the Examiner reconsider and withdraw the rejection to claims 1-49 due to double patenting or provide some clear evidence to establish why PH6ME would have been obvious over PH1EM. See *In re Kaplan*, 789 F. 2d 1580, 229 U.S.P.Q. 683.

#### REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

3) Examiner rejects claims 1-49 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner states that, "The recitation 'PH6ME' in claims 1, 6, 12, 14, 21, 25, 31, 33, 37, 40-42, and 44-46 render the claims and those dependent thereon indefinite. Since the name 'PH6ME' is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination.... Amending claims 1, 6, 21, 25, 37, and 40 to include recite the ATCC deposit number in which seed of corn inbred line PH6ME has been deposited would overcome the rejection." Claims 1, 6, 21, 25, 37, and 40 have been so amended by deleting the blank spaces and inserting the ATCC deposit number. The specification has also been amended to include the terms of the deposit for PH6ME. A copy of the ATCC deposit receipt is included in this response. These actions obviate the rejection.

Examiner states that, "In claims 14, 33, 41, 45, and 46: the terms 'excellent' and 'above average' are relative terms that have no definite meaning.... Applicants have amended claims 33 and 41 in part by removing such terms as indicated by the examiner. Claims 45 and 46 have been deleted. Applicants have amended claim 14 to

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read, " A maize plant, or parts thereof, wherein at least one ancestor of said maize plant is the maize plant of claim 2, said maize plant expressing a combination of at least two PH6ME traits which are not significantly different from PH6ME traits when determined at the 5% significance level and when grown in the same environmental conditions, said PH6ME traits selected from the group consisting of: a relative maturity of 109 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, grain yield, Fusarium Ear Mold resistance, Gray Leaf Spot resistance, Northern Leaf Blight resistance, brittle stalk resistance, and artificial brittle stalk resistance; and wherein said at least two PH6ME traits were not exhibited by other plants utilized in the development of said maize plant." Applicants point out that claim 14 has been amended to clearly define the traits of PH6ME that could be found in a maize plant produced from PH6ME. Applicants have amended the claim using the term "not significantly different from PH6ME traits when determined at a 5% significance level..." as a definitive term. In the specification pages 39-55, the tables show mean trait values. The standards against which the listed traits should be compared are the mean values for those traits exhibited by PH6ME or a maize plant produced from PH6ME in a side-by-side comparison or under other similar environmental conditions. For example, on page 37, Table 2A, the data shows that PH6ME demonstrated significantly higher resistance to Fusarium ear and kernel rot than PH24E. The Applicants would also like to point out that one of ordinary skill in the art of plant breeding would know how to evaluate the traits of two inbred maize lines to determine if they are not significantly different to a 5% significance level in the expression of a given trait. On pages 275-276 in Principles of Cultivar Development (1987) Fehr writes "Two or more independent comparisons of lines in a test provide a means of estimating whether variation in performance among lines is due to differences in genetic potential or to environmental variation." A copy of Fehr, pages 261-286, is attached to this Amendment and Request for Reconsideration as Appendix A. As was done by the Applicants in the specification, mean trait values would be used to determine whether the trait differences are significant. Further, the claims, as amended, require that the traits be measured on plants grown in the same environmental conditions. These amendments obviate the rejection.

Examiner states that, "In claims 16 and 35: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the corn plant breeding program of claims 15 and 35, respectively. However, claims 15 and 35 are directed to methods not programs. It is suggested that the recitation 'corn plant breeding program'

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in line 1 of claims 16 and 35 be replaced with --method--." Claims 16 and 35 have been so amended thus obviating the rejection.

Examiner states that, "In claims 19, 20, 48, and 49: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the single gene conversion(s) of claims 18 or 47. However, claims 18 and 47 are directed to maize plants." Applicants have amended claims 19 and 20 that depend from claim 18 and claims 48 and 49 that depend from claim 47, thus obviating the rejection.

Applicants point out that claims 4 and 23 have been amended to delete the words "of regenerable" and now read, "A tissue culture of cells from the plant of claim 2 [21]." These amendments were made for clarification purposes.

Applicants point out that claims 5 and 24 have been amended to delete the word "the" and inserted the words "of the tissue culture". These amendments were made for clarification purposes. Amendments to claims 11, 12, 13, 18, 31 and 32 have been made for clarification purposes also.

#### REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

4) Examiner states that, "Claims 3, 9-14, 17-20, 22, 28-33, 36-39, 41-49 are rejected under 35 U.S.C.112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants traverse these rejections.

The Examiner goes on to state, on the bottom of page 6 of the Office Action dated August 6, 2002, that, "...the specification does not describe PH6ME as being male sterile. The specification discusses how plants may be manipulated to be male sterile (page 2, line 21 to page 3, line 14). However, the morphological and physiological description of plant PH6ME described in the specification does not indicate that it is male sterile." Applicants point out that the specification describes how plants may be manipulated to be male sterile, not only on page 2, line 21 to page 3, line 14, but also on page 1, line 35 through line 14 on page 3; and in the section Further Embodiments of the Invention, page 21 lines 32-34. On page 21, lines 32-34, it states, "It should be understood that the inbred can, through routine manipulation of cytoplasmic or other factors, be produced in a male-sterile form. Such embodiments are also contemplated within the scope of the present claims." On page 2, line 1, the specification reads, "There are several options for controlling male fertility available to

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breeders, such as: manual or mechanical emasculation (or detasseling), cytoplasmic male sterility, genetic male sterility, gametocides and the like." The specification goes on to give examples and references. These processes are known to one of ordinary skill in the art and are routine manipulations to inbred PH6ME. Claims 3 and claim 22 have been amended and now read, "The plant of claim 2 (21), wherein said plant has been manipulated to be male sterile." The foregoing arguments and the amendments to claims 3 and 22 obviate the Examiner's rejection to claims 3 and 22.

The Examiner also categorically rejects product claims encompassing any modification of PH6ME, no matter how minor the modification or routine the modification is for a breeder of ordinary skill in the art to make.

As noted in the specification, the development of an inbred line is a time consuming and labor intensive activity. On average, between 10,000 to 20,000 lines are created and screened in order to develop any maize inbred line for which Applicants file a patent application. Once developed, the inbred line is useful for two purposes: (1) to make commercial hybrids, and (2) as a source of breeding material for the development of new inbreds that retain its desired characteristics. A breeder desiring to make a line with similar traits to PH6ME would be greatly advantaged by being able to use PH6ME as starting material. This is because the linked genes arranged through Applicants' breeding efforts, and fixed in PH6ME, can be maintained in the progeny of PH6ME by a breeder of ordinary skill in the art. For example, if a breeder of ordinary skill in the art desired an early maturity version of PH6ME, the breeder could cross PH6ME to an earlier maturing variety, select for progeny with at least two desired PH6ME traits that also express early maturity, and continue selecting for the traits of PH6ME combined with early maturity. Optionally, the breeder could backcross to PH6ME to obtain further genetic contribution from PH6ME. The end result is the development of an inbred line with substantially all of the benefit of Applicants' work but with only a fraction of the effort.

Specifically, in rejecting the claims for lack of written description, the Examiner states, "The specification also does not describe the plants that can be produced by the corn breeding programs, transgenic PH6ME plants, PH6ME plants comprising single gene conversion(s), or by crosses wherein at least one ancestor is the corn variety PH6ME, other than PH6ME/PH21T. The morphological and physiological traits of the corn plants that are crossed with PH6ME, and with progeny of that cross, are unknown, and the description of progeny and descendants of corn plant PH6ME are unknown.

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The description of PH6ME is not indicative of the description of plants and seed produced by the breeding programs and crosses, or any of its descendants. The claimed invention also encompasses plants that express at least two 'PH6ME traits' listed in claims 14, 33, 41, 45, and 46. However, to say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by PH6ME. Two plant traits do not provide any description of the other traits of the plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant PH6ME. For, example, Noble, Jr. (U.S. Patent No. 6,118,056) describes a corn plant, designated 'PH1EM,' which has at least two traits in common with PH6ME, a relative maturity of 109 based on the Comparative Relative Maturity Rating System from harvest moisture of grain, and above average resistance to Gray Leaf Spot, for example (col. 10, lines 52-62). The instantly claimed corn plants could have PH1EM as an ancestor, as well as PH6ME, in which case the relative maturity and Gray Leaf Spot, for example, could have been inherited from PH1EM. The claims also encompass plants that do not have to express any of the traits that are expressed by PH6ME."

Applicants note that Examiner's comments represent an abrupt and undocumented change of patent office policy. In numerous previous cases involving the protection of germplasm and progeny claims, including cases allowed after the recently adopted written description guidelines, the listing of traits was previously required by the patent office as a way to meet the written description requirement with respect to progeny. One reason for using traits as a means of description is because it was, and still is, technologically impossible to sequence the entire genome of a specific variety.

If it was possible to sequence the genome of a variety, PH6ME could be described and compared to the prior art to identify its unique genetic sequences and sequence combinations, and presumably, claims to progeny retaining those unique genetic aspects would be allowed by the patent office. This would be analogous to the way claims are examined for individual short genetic sequences and claims allowed for any plant comprising a specific transgene. Applicants assert that the fact that technological tools do not exist to fully describe the unique characteristics of the full genome of PH6ME does not make the progeny lines derived therefrom any less entitled to adequate patent protection. It is the purpose of the patent law to protect new and useful processes, compositions of matter and improvements thereof. 35USC 101.

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This situation is somewhat analogous to *Ex Parte Tanksley*, 37 USPQ2d. 1382. In that case the Examiner desired that Tanksley claim according to sequence data to "better characterize the cDNA clones" and "facilitate a complete search of the prior art" and issued a 112 first paragraph written description rejection. The Board held that "the section 112 rejection amounts to a requirement...that the appellants amend their claims in a specified manner...We find no language in the statute or case law which would support that requirement." The Board, in treating the section 112 first paragraph rejection as a 112 second paragraph rejection, held that "In our judgement, a patent applicant is entitled to a reasonable degree of latitude in complying with the second paragraph of 35 U.S.C. 112 and the examiner may not dictate the literal terms of the claims for the stated purpose of facilitating a search of the prior art. Stated another way, a patent applicant must comply with 35 U.S.C. 112, second paragraph, but just how the applicant does so, within reason, is within applicant's discretion." *Id.* at 1386.

Applicants have amended claims 17, 33 and 36 to limit the progeny covered to those within a pedigree distance of two crosses away from PH6ME. Claim 41 is limited to one cross away from PH6ME by virtue of dependency. Within the plant breeding arts breeders use pedigree as a means to characterize lines in reference to their progenitors. To those of ordinary skill in the art, this indicates that a line fewer crosses away from a starting line will be, as a whole, more highly related to the starting line. Thus, the work of the original breeder in developing the starting line will be retained in the closely related progeny. More specifically, traits and linkage groups present in PH6ME will be retained in progeny that are within 2 outcrosses from PH6ME. Applicants submit that characterization of the progeny of PH6ME by virtue of their filial relationship is clearly within reason. Not only are filial descriptions used by breeders to evaluate materials for use in their breeding programs, but it is standard practice within the plant breeding industry for licensor's of inbred maize lines to retain a royalty from lines developed through the use of their inbreds. Those royalties are, in almost all cases, based on the filial relationship between the licensed inbred used in breeding and the progeny line commercialized. This provides evidence that those of ordinary skill in the art of plant breeding describe progeny in terms of pedigree.

Applicants also note that the mere fact that the progeny have not been created does not prevent them from being patented. As stated in MPEP 2163 (3) (a), "An invention may be complete and ready for patenting before it has actually been reduced to practice." As stated in the written description guidelines "an applicant shows

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possession of the claimed invention by describing the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways, including...by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention." 1255 Official Gazette 140 (Feb. 5, 2002). Pedigree, which is a formula used by plant breeders, is a distinguishing identifying characteristic in compliance with the written description guidelines. Further, the Examiner must evaluate written description by the claimed invention with all of its limitations, including the limitation of being derived from PH6ME.

PH6ME-derived progeny are described by the fact that PH6ME is utilized in a breeding program to make the PH6ME-derived progeny, PH6ME gives genetic contribution to the PH6ME-derived progeny, and the genetics of PH6ME are described by ATCC deposit of PH6ME seed. By limiting the progeny to 2 or less crosses away from PH6ME, the Examiner's concern that the progeny may be only distantly related to PH6ME is addressed. In *Enzo vs. Gen-Probe*, U.S. State Court of Appeals for the Federal Circuit, 63 USPQ 2d 1609, the court reversed its prior decision regarding the insufficiency of the deposited genetic probes to meet the written description requirement. In so holding, the court stated, "As the deposited sequences are about 850, 8500, and 1300 nucleotides long, ..., there are at least hundreds of subsequences of the deposited sequences, an unknown number of which might also meet the claimed hybridization ratio. Moreover, Enzo's expert, Dr. Wetmur, stated that 'astronomical' numbers of mutated variations of the deposited sequence also fall within the scope of those claims, and that such broad claim scope is necessary to adequately protect Enzo's invention from copyists who could otherwise make minor change to the sequence and thereby avoid infringement while still exploiting the benefits of Enzo's invention. The defendants assert that such breadth is fatal to the adequacy of the written description. On the other hand, because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art. We regard that question as an issue of fact...."

The issue of whether the progeny as now claimed satisfies the written description requirement is also an issue of fact. One of ordinary skill in the art would know if PH6ME were utilized in a breeding program by looking at the breeding records

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and therefore would know if a progeny were derived from PH6ME. PH6ME is a unique inbred, as evidenced by the morphological and physiological traits given in Table 1, pages 18-20, of the application. Routinely used molecular techniques, discussed on page 16, line 8, through page 17, line 2, of the Application, can be used to verify whether PH6ME is within the pedigree of a line.

Applicants would also like to emphasize that PH6ME cannot be derived through any other means than through PH6ME seed and plant, nor can the influence of PH6ME on the progeny be removed from a line within 2 outcrosses of PH6ME. This fact also highlights the different perspective between the Examiner and the Applicants regarding the scope of the claims. The Examiner believes the claims to progeny to be of great breadth. However, to view these claims as being of great breadth merely because a large number of plants could theoretically fall within its scope ignores an essential limitation of the claim; that only a plant developed through the use of PH6ME is within the scope of the claim. Such a plant could not be independently derived without the use of PH6ME, so the claim would not in any way restrict the work of a breeder that did not in fact use PH6ME. A breeder infringing such a claim must have made a conscious choice to use PH6ME in order to obtain some or all of PH6ME's desired characteristics. Compliance with the written description requirement is essentially a fact based inquiry that will "necessarily vary depending on the nature of the invention claimed." Vas-Cath v. Mahurkar, 935 F. 2d 1555 (citing *In re DiLeone*, 436 F2d. 1404, 1405). Thus, the compliance with the written description requirement must be judged in view of this limited scope of the progeny claims. As amended, the claims are drawn to only a limited scope of progeny, progeny which but for Applicants' creation of PH6ME could never have existed. This is in harmony with the statement in section 2163 of the MPEP that "the written description requirement promotes the progress of the useful arts by ensuring inventions are adequately described in the specification in exchange for the right to exclude." That quid pro quo of patent law has been met by the Applicants in the present case, and to use written description to deny adequate patent protection would be contrary to the stated purpose of the written description requirement.

Applicants point out that, to overcome the Examiner's rejection, claim 14 has been amended in a different manner. The Examiner has expressed concern that the PH6ME traits retained by the progeny may be derived from the non-PH6ME side of the pedigree. To address this concern, Applicants have amended claim 14 to specify that

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the "at least two PH6ME traits" were not exhibited by other plants utilized in the development of said maize plant.

In addition to the progeny claims, the Examiner issued additional written description rejections under 35 U.S.C.112, first paragraph as follows: "The description of the PH6ME/PH21T hybrid also does not provide any information concerning the description of any other hybrids." It is well known to anyone skilled in the art that a hybrid has a genome with one set of the alleles from each inbred. Thus the F1 hybrid claimed contains essentially all of the alleles of PH6ME. Therefore the genetic profile exhibited in the deposit would be exhibited in the hybrid. The genetic profile of the other plant used to make the hybrid would also be present because an F1 contains one set of chromosomes from each parent. As stated in the specification on page 16, lines 8-15, there are many laboratory based techniques available for the analysis comparison and characterization of plant genotype such as Restriction Length Polymorphisms (RFLPs) and Simple Sequence Repeats (SSRs). Such techniques have been known for some time and may be used to identify whether or not PH6ME was used to develop a hybrid. Applicants also submit to the Examiner the journal article by Berry et al. (2002). This article discusses the probability of identifying the parents of the hybrid by SSR data when neither parent is known. A copy of article by Berry et al. is attached to this Amendment and Request for Reconsideration as Appendix B. The results of the experiment showed that using 100 SSR loci markers resulted in correct parental ranking of inbreds for 53 out of 54 hybrids. Applicants also point out that any breeder of ordinary skill in the art will know the identity of both parents used to produce a hybrid.

Applicants note that a claim to the F1 hybrid made with a deposited inbred was expressly acknowledged without reservation by the United States Supreme Court In *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 60 USPQ 2d 1865,1873 (S.Ct. 2001), when the Supreme Court wrote, "...a utility patent on an inbred plant line protects the line as well as all hybrids produced by crossing that inbred with another plant line."

The Examiner goes on to reject claims to PH6ME plants further containing transgenes and single gene conversions under 35 U.S.C.112, first paragraph. The Examiner states, "Transgenes may also be of any gene, including those that effect more than one trait. The morphological and physiological characteristics of any such plant are not described. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits."

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Applicants note examples of traits and single gene conversions are given in the specification, page 21, lines 16-31, and page 22, line 34, thru page 33, line 4. Even if more than one trait is affected by the transgene, the genetics of PH6ME will be only minimally affected. The Examiner must consider all limitations of the claimed invention. While the Examiner is focusing on traits, the Applicants point out that they are not claiming so broadly as to claim any maize plant, regardless of source, comprising those traits. Applicants are claiming PH6ME, or a limited set of plants derived therefrom, that retain significant features of PH6ME. Applicants have made an enabling deposit of PH6ME with the ATCC, and Applicants are seeking a fair scope of protection as the quid pro quo for the teaching in the specification and the deposit of the material. The insertion of one or a few genes into a genome that is estimated to have over 50,000 to 80,000 genes (Xiaowu, Gai et al., Nucleic Acids Research, 2000, Vol. 28, No. 1, 94-96) is a minor change to PH6ME and will not prevent one of skill in the art from identifying the plant as PH6ME. In addition, to expedite prosecution, Applicants have amended claims 30 and 47. They now include the limitation that the maize plant, or parts thereof, are essentially unchanged from the corresponding plant, or parts thereof, of inbred line PH6ME.

Lastly, the Examiner has rejected certain method claims under written description. Applicants point out that the methods are fully described, as is the starting material in the method, PH6ME. One of ordinary skill in the art would know how to cross PH6ME to develop an F1 hybrid and also how to self plants derived from crosses with PH6ME for the purpose of developing an inbred plant. In *Ex parte Parks*, 30 USPQ 2d 1234 (B.P.A.I. 1994), the Board of Appeals stated, "Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." In *J.E.M. Ag. Supply*, the Supreme Court also acknowledged the value of a utility patent in protecting the use of the line in breeding, when it stated that, "...a breeder can use a plant that is protected by PVP certificate to 'develop' a new inbred line while he cannot use a plant patented under §101 for such a purpose." *Id.* at 1873. In light of the amendments to the claims and the foregoing arguments the Applicants request reconsideration of the rejection under the first paragraph of 35 U.S.C. 112.

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**REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

5) Examiner rejects claims 1-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 6, 21, 25, 37, and 40 have been amended by deleting the blank spaces and inserting the ATCC deposit number. The specification has also been amended to include the terms of the deposit for PH6ME. A copy of the ATCC deposit receipt is included in this response. In light of the amendments to the claims and the specification the Applicants request reconsideration of the rejection under the first paragraph of 35 U.S.C. 112.

**REJECTIONS UNDER 35 U.S.C. § 102 and 103**

6) Examiner states that, "Claims 1-49 are rejected under 35 U.S.C. 102(e) as anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Noble, Jr. (U.S. Patent No. 6,118, 056)."

The Examiner goes on to state, "Noble, Jr. teaches seed of an inbred maize line designated 'PH1EM', plants produced by growing said seed, and plants and plant parts having all the physiological and morphological characteristics of PH1EM (col. 10, line 52 to col. 12, line 7, Table 1; claims). It appears that the claimed plants and seeds of the instant invention may be the same as PH1EM, given that they exhibit similar traits, a relative maturity of 109 based on the Comparative Relative Maturity Rating system for harvest moisture of grain, and above average resistance to Gray Leaf Spot, for example (col. 10, lines 52-62). Alternatively, if the claimed plants, plant parts, and seeds of PH6ME are not identical to PH1EM, then it appears that PH1EM only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer patentable distinction to PH6ME."

Claims 1, 6, 21, 25, 37, and 40 have been amended to include the ATCC number. Applicants again point out that PH6ME is not PH1EM, nor is PH6ME an obvious variation or anticipated variation of PH1EM. Differences are pointed out in section 2 of this response.

Applicants have cancelled claims 45 and 46.

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As stated earlier claim 14 was amended to remove such words as "excellent" and "above average". The claim was also amended to include, "and wherein said at least two PH6ME traits were derived from PH6ME and not from other plants utilized in the development of said maize plant." The claim now clearly states that PH6ME is utilized to obtain the maize plant claimed. Because PH6ME is not PH1EM nor is PH6ME obvious over PH1EM then any claimed plant derived through the use of PH6ME is non-obvious. Also of importance is that because PH6ME is not PH1EM the maize plant of claim 14 cannot be obtained by any means other than by utilizing the seed or plant of PH6ME. Applicants request that the Examiner reconsider the rejection to claim 14 under 35 U.S.C. 102(e) and 35 U.S.C. 103(a).

Applicants have amended claims 17 and 36 as follows, "A maize plant, or parts thereof, produced by the method of claim 15 (34) wherein the method comprises 2 or less crosses to a plant other than PH6ME or a plant that has PH6ME as a progenitor." Claims 17 and 36, as well as claim 33, are now limited to a maize plant two crosses away from PH6ME. The MPEP section 2143.03 states, "If an independent claim is non-obvious under 35 USC 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988)." The MPEP section 2116.01 states, "All the limitations of a claim must be considered when weighing the differences between the claimed invention and the prior art in determining the obviousness of a process or method claim." See also *In re Ochai*, 71 F.3d 1565, 37 USPQ 2d 1127 (1995) and *In re Brouwer*, 77 F. 3d 422, 37 USPQ 2d 1663 (1996). Once again, because PH6ME is not PH1EM nor is PH6ME obvious over PH1EM then any plant derived through the use of PH6ME is non-obvious. Also of importance is that progeny of PH6ME cannot be obtained by any means other than by utilizing the seed or plant of PH6ME.

Applicants have amended claims 41, 42, and 43. Claim 41 has been amended and now reads, "A PH6ME-derived maize plant, or parts thereof, produced by the method of claim 40." Claim 41 is now one cross away from PH6ME. Claim 41 clearly states that PH6ME must be used to obtain a PH6ME-derived maize plant. Claim 42 has been amended so that it does not allow any further crosses away from PH6ME. Thus claim 42 is the selfing of the plant derived by the one cross away from PH6ME made in claim 40. Claim 43 has been amended for clarification purposes. All PH6ME-derived plants are limited to one cross away from PH6ME and the derived plants are limited by the use of PH6ME in the initial cross. One would not be able to obtain plants

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within one cross of PH6ME through modification of the maize inbred taught by Noble because PH6ME comprises a unique and nonobvious combination of genetics. The claimed plants derived from PH6ME retain unique and nonobvious combinations of genetics derived from PH6ME. Thus, they deserve to be considered new and nonobvious compositions in their own right.

In light of the above, Applicants respectfully request the Examiner reconsider and withdraw the rejection to claims 1-49 under 35 U.S.C. 103(a).

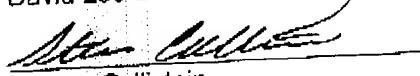
Cancellation of claims 45 and 46 and amendment of claims 1, 3, 5, 6, 14, 16, 19, 20, 21, 22, 24, 25, 33, 35, 37, 40, 41, 42, 43, 48, and 49 does not in any way change the claim scope which the Applicants believe is allowable but is meant to hasten the issuance of the patent.

#### CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

Applicants submit that in light of the foregoing amendments and the remarks, the claims 1-44, and 47-49 are in condition for allowance. Reconsideration and early notice of allowability is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

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In the specification

At page 53, the entire paragraph following "Deposits", lines 2-21, was deleted and the clean paragraph as typed was inserted.

In the claims

Claims 45 and 46 were cancelled.

Claims 1, 3, 4, 5, 6, 8, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 30, 31, 32, 33, 35, 36, 37, 40, 41, 42, 43, 47, 48, and 49 were amended as follows.

1. (Amended) Seed of maize inbred line designated PH6ME, representative seed of said line having been deposited under ATCC Accession No. [ \_\_\_\_\_ ] PTA-4529.

3. (Amended) The maize plant of claim 2, wherein said plant is manipulated to be male sterile.

4. (Amended) A tissue culture of [regenerable] cells from the plant of claim 2.

5. (Amended) A tissue culture according to claim 4, [the] cells or protoplasts of the tissue culture being from a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.

6. (Amended) A maize plant regenerated from the tissue culture of claim 4, capable of expressing all the morphological and physiological characteristics of inbred line PH6ME, representative seed of which have been deposited under ATCC Accession No. [ \_\_\_\_\_ ] PTA-4529.

8. (Amended) The method of claim 7 wherein [the inbred maize plant of claim 2] said different inbred parent maize plant is the [female or] male parent.

11. (Amended) The maize plant, or parts thereof, of claim 2, wherein the plant, or parts thereof, [have been transformed so that its] genetic material contains one or more

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transgenes operably linked to one or more regulatory elements) further comprise one or more transgenes.

12. (Amended) A method for producing a maize plant [that contains in its genetic material one or more transgenes,] comprising crossing the maize plant of claim 11 with [either] a second plant of another maize line [, or a non-transformed maize plant of the line PH6ME, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element ].

13. (Amended) [Maize plants] The maize plant, or parts thereof, produced by the method of claim 12.

14. (Amended) A maize plant, or parts thereof, wherein at least one ancestor of said maize plant is the maize plant of claim 2, said maize plant expressing a combination of at least two PH6ME traits which are not significantly different from PH6ME traits when determined at the 5% significance level and when grown in the same environmental conditions, said PH6ME traits selected from the group consisting of: a relative maturity of [approximately] 109 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, [excellent] grain yield, [excellent] Fusarium Ear Mold resistance, [above average] Gray Leaf Spot resistance, [above average] Northern Leaf Blight resistance, [above average] brittle stalk resistance, [above average] and artificial brittle stalk resistance [, and adapted to the Central Corn Belt, Northwest, Northcentral, Northeast, Western, and Drylands regions of the United States] ; and wherein said at least two PH6ME traits were not exhibited by other plants utilized in the development of said maize plant.

16. (Amended) The [maize plant breeding program] method of claim 15 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

17. (Amended) A maize plant, or parts thereof, produced by the method of claim 15 wherein the method comprises 2 or less crosses to a plant other than PH6ME or a plant that has PH6ME as a progenitor.

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18. (Amended) The maize [plants] plant, or parts thereof, of claim 2, further comprising one or more single gene conversions.

19. (Amended) The [single gene conversion(s)] maize plant of claim 18, wherein [the] at least one single gene conversion is a dominant allele.

20. (Amended) The [single gene conversion(s)] maize plant of claim 18, wherein [the] at least one single gene conversion is a recessive allele.

21. (Amended) A maize plant, or parts thereof, having all the physiological and morphological characteristics of inbred line PH6ME, representative seed of said line having been deposited under ATCC accession No. [ \_\_\_\_ ] PTA-4529.

22. (Amended) The maize plant of claim 21, wherein said plant is manipulated to be male sterile.

23. (Amended) A tissue culture of [regenerable] cells from the plant of claim 21.

24. (Amended) A tissue culture according to claim 23, [the] cells or protoplasts of the tissue culture being from a tissue selected from the group consisting of leaves, pollen, embryos, roots, root tips, anthers, silks, flowers, kernels, ears, cobs, husks, and stalks.

25. (Amended) A maize plant regenerated from the tissue culture of claim 23, capable of expressing all the morphological and physiological characteristics of inbred line PH6ME, representative seed of which have been deposited under ATCC Accession No. [ \_\_\_\_ ] PTA-4529.

27. (Amended) The method of claim 26 wherein [the inbred maize plant of claim 21] said different inbred parent maize plant is the female [or male] parent.

30. (Amended) The maize plant, or parts thereof, of claim 21, wherein the plant, or parts thereof, [have been transformed so that its genetic material contains one or more

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transgenes operably linked to one or more regulatory elements] further comprises one transgenes operably linked to one or more regulatory elements, and wherein the maize plant, or parts thereof, are essentially or more transgenes, and wherein the maize plant, or parts thereof, are essentially unchanged from the corresponding plant, or parts thereof, of PH6ME.

31. (Amended) A method for producing a maize plant [that contains in its genetic material one or more transgenes,] comprising crossing the maize plant of claim 30 with [either] a second plant of another maize line [, or a non-transformed maize plant of the line PH6ME, so that the genetic material of the progeny that result from the cross contains the transgene(s) operably linked to a regulatory element].

32. (Amended) [Maize plants] The maize plant, or parts thereof, produced by the method of claim 31.

33. (Amended) A PH6ME-derived maize plant, or parts thereof, wherein at least one ancestor of said maize plant is the maize plant of claim [21] 2, and wherein the pedigree of said PH6ME-derived maize plant is within 2 or less crosses to a plant other than PH6ME or a plant that has PH6ME as a progenitor [said maize plant expressing a combination of at least two PH6ME traits selected from the group consisting of: a relative maturity of approximately 109 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, excellent grain yield, excellent Fusarium Ear Mold resistance, above average Gray Leaf Spot resistance, above average Northern Leaf Blight resistance, above average brittle stalk resistance, above average artificial brittle stalk resistance, and adapted to the Central Corn Belt, Northwest, Northcentral, Northeast, Western, and Drylands regions of the United States].

35. (Amended) The [maize plant breeding program] method of claim 34 wherein plant breeding techniques are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

36. (Amended) A maize plant, or parts thereof, produced by the method of claim 34 wherein the method comprises 2 or less crosses to a plant other than PH6ME or a plant that has PH6ME as a progenitor.

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37. (Amended) A process for producing inbred PH6ME, representative seed of which have been deposited under ATCC Accession No. [ ] PTA-4529, comprising:

- (a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred PH6ME said collection also comprising seed of said inbred;
- (b) growing plants from said collection of seed;
- (c) identifying said inbred PH6ME plants;
- (d) selecting said inbred PH6ME plant; and
- (e) controlling pollination in a manner which preserves the homozygosity of said inbred PH6ME plant.

40. (Amended) A method for producing a PH6ME-derived maize plant, comprising:

- (a) crossing inbred maize line PH6ME, representative seed of said line having been deposited under ATCC Accession No. [ ] PTA-4529, with a second maize plant to yield progeny maize seed;
- (b) growing said progeny maize seed, under plant growth conditions, to yield said PH6ME-derived maize plant.

41. (Amended) A PH6ME-derived maize plant, or parts thereof, produced by the method of claim 40 [, said PH6ME-derived maize plant expressing a combination of at least two PH6ME traits selected from the group consisting of : a relative maturity of approximately 109 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, excellent grain yield, excellent Fusarium Ear Mold resistance, above average Gray Leaf Spot resistance, above average Northern Leaf Blight resistance, above average brittle stalk resistance, above average artificial brittle stalk resistance, and adapted to the Central Corn Belt, Northwest, Northcentral, Northeast, Western, and Drylands regions of the United States].

42. (Amended) The method of claim 40, further comprising:

- (c) [crossing] selfing or sibbing said PH6ME-derived maize plant [with itself or another maize plant] to yield additional PH6ME-derived progeny maize seed;
- (d) growing said progeny maize seed of step (c) under plant growth

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conditions, to yield additional PH6ME-derived maize plants;  
(e) repeating the [crossing] selfing and growing steps of (c) and (d) [from 0 to 5 times] to generate further PH6ME-derived maize plants.

43. (Amended) [A] The further [derived maize plant] PH6ME-derived maize plants, or parts thereof, produced by the method of claim 42.

47. (Amended) The maize [plants] plant, or parts thereof, of claim 21, further comprising one or more single gene conversions, wherein the maize plant, or parts thereof, are essentially unchanged from the corresponding plant, or parts thereof, of inbred line PH6ME.

48. (Amended) The [single gene conversion(s)] maize plant of claim 47, wherein [the] at least one single gene conversion is a dominant allele.

49. (Amended) The [single gene conversion(s)] maize plant of claim 47, wherein [the] at least one single gene conversion is a recessive allele.